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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/284,114	04/07/99	SAKAGUCHI S	07898/038001

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EXAMINER	
KERR, J	
ART UNIT	**PAPER NUMBER**
1633	7

DATE MAILED: 08/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev. 2/95)

U.S. G.P.O. 2000 ; 465-188/25266

Office Action Summary	Application No. 09/284,114	Applicant(s) Shimon Sakaguchi
	Examiner Janet M. Kerr	Group Art Unit 1633

☒ Responsive to communication(s) filed on *May 17, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-11* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-11* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Amendment

Applicant's amendment, filed on 5/17/00, has been entered.

Claims 1-11 are pending.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are/remain rejected under 35 U.S.C. 101 as the claimed invention is directed to non-statutory subject matter, for the reasons of record and the reasons below. The claims are drawn to an SKG mouse which has not been altered by the hand of man, and is a naturally occurring animal. The claims read on a product of nature which is non-statutory subject matter.

Applicant's arguments filed 5/17/00 have been fully considered but they are not persuasive. Applicant argues that the SKG mouse is from a BALB/c strain of mouse, an albino, inbred strain originally developed by the hand of man and which does not occur in nature, and thus, the SKG mouse is from an inbred strain of mouse produced by the hand of man that does not exist in nature. Applicant also refers to section 2105 of the MPEP which states that "[T]he production of articles for use from raw materials prepared by giving to these new forms, qualities, properties or combinations, whether by hand labor or by machinery is a manufacture under 35 U.S.C. 101. In this regard, applicant argues that the SKG mouse itself has new properties and was obtained from a BALB/c strain given "new forms, qualities, and properties" and is thus statutory subject matter. In addition, applicant refers to the claims of U.S. Patent No. 6,040,495 which are directed to a particular type of NS:Hr/ICR hairless mouse susceptible to *Heliobacter pylori* infection, obtained by breeding a male hairless ICR mouse with a female hairless mouse. Applicant indicates that the NS:Hr/ICR hairless mouse susceptible to *Heliobacter pylori* of the patent has a special character as an experimental animal apart from hairless mice in general and, therefore appears to be a

mutant offspring of hairless mice. Applicants assert that by analogy to the hairless mouse which was identified from a breeding of two hairless mice that do not occur in nature, the SKG mouse having natural onset of autoimmune arthritis of the instant application was identified from a breeding of two BALB/c mice that do not occur in nature. As such, applicant argues that the SKG mouse, like the NS:Hr/ICR hairless mouse, is patentable subject matter.

These arguments are not persuasive. There is no indication in the specification that the SKG mouse has been altered in any way by the inventor. In fact, the specification states, on page 4, last paragraph, that

"a female mouse with joint swelling was found in an inventor's BALB/c colony (purchased in 1992 from Nippon SLC) in the Institute for Physical and Chemical Research. This joint swelling was assumed to be due to a genetic mutation; and this mutant strain was designated as SKG.".

There is no suggestion in the specification that the mutation is a result of any type of intervention by applicant to provide a mouse displaying a phenotype which would be useful as a model for a particular disease state. Thus, applicant did not produce an article for use from raw materials prepared by giving to the article new forms, qualities, properties or combinations, by hand labor or by machinery. Applicant merely observed a mouse with joint swelling in a mouse colony purchased from a company. With regard to the hairless mouse, it should be noted that sibling mice were bred for 70 generations to produce a strain of mouse susceptible to *Heliobacter pylori* infection. There is no suggestion in U.S. Patent No. 6,040,495 that the original ICR mice were as susceptible to *Heliobacter pylori* than the inbred strain developed over a period of 70 generations. As stated above, applicant indicates that the NS:Hr/ICR hairless mouse susceptible to *Heliobacter pylori* of the patent has a special character as an experimental animal apart from hairless mice in general. In this regard, the specification teaches that SKG mouse was initially observed in the colony, and further that while the BALB/c mice were thought to be normal, the mice, in fact displayed symptoms of rheumatoid arthritis, i.e., joint swelling was noted in the small joints of the fingers. Thus, the mutation(s) which causes the rheumatoid arthritis phenotype was

already present in the population of BALB/c mice. Applicant did not specifically mutate or alter the mouse genotype, by selective breeding or other techniques, to produce a mouse having a special character as an experimental animal apart from the BALB/c mouse colony purchased from Nippon SLC. Thus, for the reasons set forth above, the rejection under 35 U.S.C. 101 is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an SKG BALB/c mouse strain that develops natural onset rheumatoid arthritis, and methods of producing and using the mouse strain, does not reasonably provide enablement for an SKG BALB/c mouse strain that develops natural onset of autoimmune arthritis, and methods of producing and using the mouse strain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to a BALB/c mouse strain, denoted SKG, that naturally develops autoimmune arthritis, methods of producing mice using the claim-designated strain, and a method of identifying a therapy that decreases a symptom of rheumatoid arthritis using the claim-designated strain.

While the specification is enabling for the mouse strain that naturally develops rheumatoid arthritis, the specification is not enabling for a mouse strain that naturally develops autoimmune arthritis. The claimed mice and methods of use are not commensurate in scope with the teachings in the specification. The specification teaches that the mouse strain normally develops

symptoms/pathologies which are similar to human rheumatoid arthritis in morbid conditions. Such symptoms/pathologies include chronic progression from the appearance of pannus to the inflammatory destruction of joint cartilage and bone accompanied by lymphocyte infiltration; the small and large joints of the forelegs and hind legs are affected symmetrically, and the lesions chronically progress and finally lead to joint stiffening; rheumatoid factor, autoantibody against type II collagen specific for joints, and hypergammaglobulinemia frequently develop. However, the specification does not disclose any other types of autoimmune arthritis which are present in the claim-designated mouse strain, or other mice obtained from breeding the claim-designated mouse strain with BALB/c mice or non-BALB/c mice strains, nor does the specification disclose symptoms associated with autoimmune arthritis other than those observed with rheumatoid arthritis. In addition, the specification does not provide any guidance or working examples as to how to make other mice strains which display symptoms/pathologies associated with autoimmune arthritis other than those observed with rheumatoid arthritis. Thus, in view of the lack of guidance and working examples, it would require undue experimentation for the skilled artisan to make and use the mice as claimed.

Claims 1-5 are/remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record and the reasons set forth below.

Claims 1-5 are directed to a mouse strain. As stated in the previous office action, the embryos of the mice must be deposited as set forth in the MPEP 2402-2411 and 37CFR 1.801-1.809.

Applicant's intent to comply with the deposit requirements upon indication of allowable subject matter (see page 5 of applicant's Response) is acknowledged.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 5, 6, 8, and 10 are rendered vague and indefinite by the phrase "autoimmune arthritis" as the specification only discloses symptoms associated with rheumatoid arthritis. As autoimmune arthritis encompasses rheumatoid arthritis, but is not limited to rheumatoid arthritis, it is unclear what symptoms are displayed or what the phenotype is displayed in a mouse afflicted with autoimmune arthritis.

Claim 10 is confusing because it is unclear how determining whether a potential therapy decreases a symptom of autoimmune arthritis identifies a therapy that decreases a symptom of rheumatoid arthritis. While autoimmune arthritis encompasses rheumatoid arthritis, symptoms associated with autoimmune arthritis are not restricted to rheumatoid arthritis, thus a symptom of autoimmune arthritis is not necessarily a symptom of rheumatoid arthritis. It is unclear what the nexus is between identification of a therapy that decreases a symptom of autoimmune disease and identification of a therapy that decreases a symptom of rheumatoid arthritis.

Applicant's arguments filed 5/17/00 have been fully considered but they are not persuasive. Applicant argues that the meaning of the term "autoimmune arthritis" is not vague and indefinite in view of the teachings in the specification. Applicant argues that the specification discloses physiological and morphological features that are characteristic of autoimmune arthritis. This is not persuasive as the physiological and morphological features that are disclosed in the specification are characteristic of a specific type of arthritis, i.e., rheumatoid arthritis. As there are no other symptoms or features disclosed in the specification which specifically define autoimmune

arthritis as opposed to rheumatoid arthritis. The metes and bounds of the phrase "autoimmune arthritis", with respect to physiological and morphological features of the broader classification of arthritis, are unclear.

Claims 6-11, directed to methods of using the SKG mouse, would be deemed allowable if applicant overcomes the 35 U.S.C. 112 first and second paragraph rejections of record as there is no teaching or suggestion in the prior art to use the SKG mouse in methods of breeding to produce progeny which display symptoms associated with rheumatoid arthritis, or in methods of identifying potential therapies for decreasing symptoms associated with rheumatoid arthritis.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet M. Kerr whose telephone number is (703) 305-4055. Should the examiner be unavailable, inquiries should be directed to John LeGuyader, Supervisory Primary Examiner of Art Unit 1633, at (703) 308-0447. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Janet M. Kerr, Ph.D.
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